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| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |   | ATTORNEY'S DOCKET NUMBER<br>20747/340<br>U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/593245</b> |
| INTERNATIONAL APPLICATION NO.<br>PCT/GB2005/001136  | INTERNATIONAL FILING DATE<br>18 March 2005 (18.03.2005) | PRIORITY DATE CLAIMED<br>18 March 2004 (18.03.2004)  |
| TITLE OF INVENTION EFFERVESCENT FORMULATIONS COMPRISING DESMOPRESSIN  |   |  |
| APPLICANT(S) FOR DO/EO/US LARSEN, Finn  |   |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |   |  |
| 1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.<br>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.<br>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.<br>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).<br>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<br>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).<br>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.<br>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).<br>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).<br>a. <input type="checkbox"/> is attached hereto.<br>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).<br>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<br>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> have been communicated by the International Bureau.<br>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.<br>d. <input checked="" type="checkbox"/> have not been made and will not be made.<br>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).<br>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).<br>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).<br><b>Items 11 to 20 below concern document(s) or information included:</b><br>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.<br>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.<br>13. <input checked="" type="checkbox"/> A preliminary amendment.<br>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.<br>15. <input type="checkbox"/> A substitute specification.<br>16. <input type="checkbox"/> A power of attorney and/or change of address letter.<br>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.<br>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).<br>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). |   |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

|  |   |   |   |      |              |            |   |         |                    |         |   |         |           |  |
|--|---|---|---|------|--------------|------------|---|---------|--------------------|---------|---|---------|-----------|--|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)<br><b>10/593245</b>  | INTERNATIONAL APPLICATION NO.<br><b>PCT/GB2005/001136</b> | ATTORNEY'S DOCKET NUMBER<br><b>20747/340</b>                                  |   |      |              |            |   |         |                    |         |   |         |           |  |
| 20. Other items or information:<br><b>UNSIGNED Combined Declaration and Power of Attorney</b>  |   |   |   |      |              |            |   |         |                    |         |   |         |           |  |
| The following fees have been submitted   |   | CALCULATIONS      PTO USE ONLY  |   |      |              |            |   |         |                    |         |   |         |           |  |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300  | \$ 300.00   |   |   |      |              |            |   |         |                    |         |   |         |           |  |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))<br><br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0<br>All other situations..... \$200  | \$ 200.00   |   |   |      |              |            |   |         |                    |         |   |         |           |  |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))<br>If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0<br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100<br>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400<br>All other situations..... \$500 | \$ 400.00   |   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <b>TOTAL OF 21, 22 and 23 =</b>  |   | 900.00  |   |      |              |            |   |         |                    |         |   |         |           |  |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).<br>The fee is \$250 for each additional 50 sheets of paper or fraction thereof   |   |   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Total Sheets</td> <td style="width: 15%;">Extra Sheets</td> <td style="width: 40%;">Number of each additional 50 or fraction thereof (round up to a whole number)</td> <td style="width: 30%;">RATE</td> </tr> <tr> <td style="text-align: center;">28 - 100 =</td> <td style="text-align: center;">-72 / 50 =</td> <td></td> <td style="text-align: center;">x \$250</td> </tr> </table>  | Total Sheets  | Extra Sheets  | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | 28 - 100 =   | -72 / 50 = |   | x \$250 | \$ 0.00            |         |   |         |           |  |
| Total Sheets   | Extra Sheets  | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE  |      |              |            |   |         |                    |         |   |         |           |  |
| 28 - 100 =   | -72 / 50 =  |   | x \$250   |      |              |            |   |         |                    |         |   |         |           |  |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  |   | \$ 130.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">CLAIMS</td> <td style="width: 15%;">NUMBER FILED</td> <td style="width: 15%;">NUMBER EXTRA</td> <td style="width: 15%;">RATE</td> </tr> <tr> <td>Total claims</td> <td style="text-align: center;">23 - 20 =</td> <td style="text-align: center;">3</td> <td style="text-align: center;">x \$ 50</td> </tr> <tr> <td>Independent claims</td> <td style="text-align: center;">2 - 3 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$200</td> </tr> </table>                 | CLAIMS  | NUMBER FILED  | NUMBER EXTRA  | RATE | Total claims | 23 - 20 =  | 3 | x \$ 50 | Independent claims | 2 - 3 = | 0 | x \$200 | \$ 150.00 |  |
| CLAIMS   | NUMBER FILED  | NUMBER EXTRA  | RATE  |      |              |            |   |         |                    |         |   |         |           |  |
| Total claims   | 23 - 20 =   | 3   | x \$ 50   |      |              |            |   |         |                    |         |   |         |           |  |
| Independent claims   | 2 - 3 =   | 0   | x \$200   |      |              |            |   |         |                    |         |   |         |           |  |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |   | \$ 0.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |   | \$ 1,180.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.   |   | 0.00  |   |      |              |            |   |         |                    |         |   |         |           |  |
| <b>SUBTOTAL =</b>  |   | \$ 1,180.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  |   | \$ 0.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <b>TOTAL NATIONAL FEE =</b>  |   | \$ 1,180.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   |   | \$ 0.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
| <b>TOTAL FEES ENCLOSED =</b>   |   | \$ 1,180.00   |   |      |              |            |   |         |                    |         |   |         |           |  |
|  |   | Amount to be refunded \$  |   |      |              |            |   |         |                    |         |   |         |           |  |
|  |   | Amount to be charged \$   |   |      |              |            |   |         |                    |         |   |         |           |  |

10/593245  
IAP9/Rec'd PCT/PTO 18 SEP 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

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A duplicate copy of this sheet is enclosed.
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**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

Edwin V. Merkel  
NAME

40,087  
REGISTRATION NUMBER

**EXPRESS MAIL CERTIFICATE**

DOCKET NO.: 20747/340

APPLICANT(S): LARSEN et al.

TITLE: EFFERVESCENT FORMULATIONS COOMPRISING DESMOPRESSIN

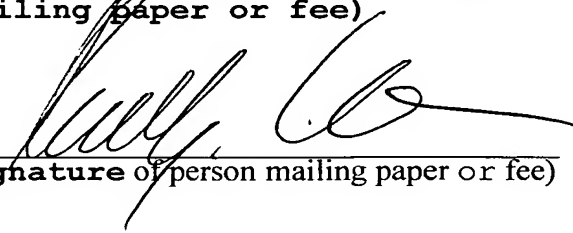
Certificate is attached to the Transmittal Letter to the U.S. Designated/Elected Office (DO/EO/US) of the above-named application.

"EXPRESS MAIL" NUMBER: E1983812392US

DATE OF DEPOSIT: September 18, 2006

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**EXPRESS MAIL CERTIFICATE**

DOCKET NO.: 20747/340

APPLICANT(S): LARSEN et al.

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Certificate is attached to the Application Data Sheet (3 pages) of the above-named application.

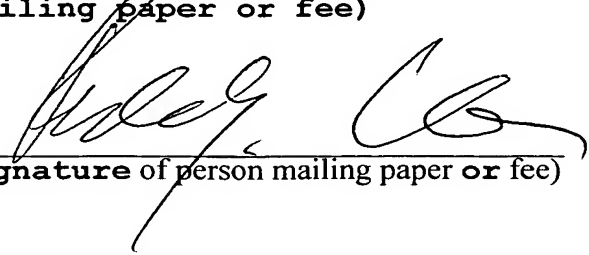
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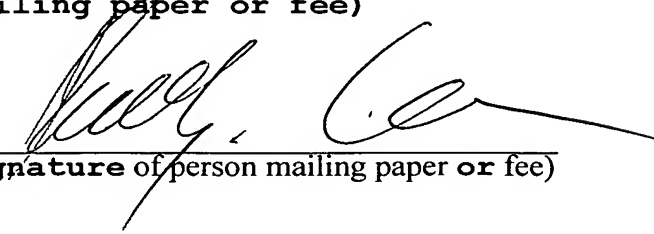
Certificate is attached to the Preliminary Amendment  
(6 pages) of the above-named application.

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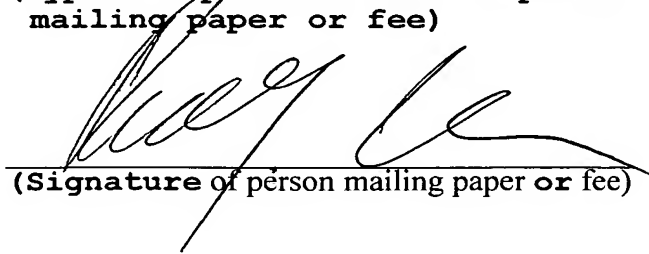
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IAP9 Rec'd PCT/PTO 18 SEP 2006

**EXPRESS MAIL CERTIFICATE**

DOCKET NO.: 20747/340

APPLICANT(S): LARSEN et al.

TITLE: EFFERVESCENT FORMULATIONS COOMPRISING DESMOPRESSIN

Certificate is attached to the Information Disclosure Statement w/PTO/SB/08form and PCT Search Report of the above-named application.


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